PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Nguyen et al. Examiner: Woo, Julian W.

Serial No.: 10/718,236 Group Art Unit: 3773

Filing Date: November 19, 2003 Docket No.: P0021779.02

Title: MINIMALLY INVASIVE VALVE REPAIR PROCEDURE AND APPARATUS

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Final Office Action dated June 15, 2009, Applicants request a pre-appeal brief review because of clear errors in the Examiner's rejections. This paper is being filed together with a Notice of Appeal. A request for a one month extension of time is being made via the EFS-web concurrently herewith thereby moving the deadline for response to October 15, 2009.

The Office Action advanced that Northrup discloses in Figures 4-9 and col. 4, lines 5-54 a clip assembly and a method of holding two tissue parts together where the assembly and method include two clips (60) each having two end points…two tissue penetrating needles (40) each releasably connected to one of the two end points…and a "structure" (e.g. 310 in Fig. 9) connecting the other end points of the two clips together; where the method includes penetrating and completely pulling one of the needles through a tissue part (e.g. 320 in Fig. 9) and penetrating an completely pulling the other of the needles through an adjacent tissue part (e.g. also at 320) while the clips are each in an open configuration and pulling the needles until each of the clips is hooked to a corresponding one of the tissue parts and where the two tissue parts are held together by the flexible connector stretched between the clips.

Contrary to this assertion, Northrup does not disclose an individual clip assembly having two tissue penetrating needles and two clips each connected at one end point to a needle through

a flexible member and connected at the other end points by a flexible connector. Fig. 9 of Northrup shows an end-to-end anastomosis being made using two *separate* clip assemblies, each having a single suture 20, a single needle 40, and a single holding device 60. Neither of these clip assemblies individually has two tissue penetrating needles as recited in independent claims 17 and 20 from which claims 19, 22, 26 and 28 depend either directly or indirectly. Further, Applicants maintain that the assertion in the Office Action that element 310 in Fig. 9 of Northrup forms part of the claimed clip assembly appears misplaced. Element 310 is a structure such as a vessel, which the two *discrete* clip assemblies join. The structure does not form part of a clip assembly. And it is improper to continue to construe the rejected claims as including body parts. The Office Action asserts that the vascular structure 310, when modified with the teachings of Krajicek is a "flexible connector" connecting the end points of the two clips together. The Office Action goes on to assert that when the clips are directly attached to a prosthesis as taught by Krajicek, the ends of the clips are connected by virtue of the attachment of both clips to the blood vessel prosthesis. However, there is nothing in Krajicek that suggests adding a prosthesis to either of the clips of Northrup or how such an addition would provide the claimed assembly. The Office Action does not explain how such a modification would be carried out, let alone why one would add a prosthesis to the surgical clip of Northrup. For example, nothing in the Office Action explains how the end-to-end anastomosis method shown in Northrup's figure 9 would be carried out if one were to attach a prosthesis to one of the clips of Northrup. In column 5, lines 32-37, it states: "Once sutures 20 are appropriately placed, sutures 20 can be "parachuted" by pulling the respective vascular structures apart, in order to check for proper positioning and spacing of sutures 20 and/or holding devices 60. This also enables the surgeon to check for crosses, tangles, etc. in sutures 20 themselves."

Furthermore, Pyka does not serve to remedy the deficiencies of Northrup. Even if the clip of Pyka were to be applied to the device of Northrup, there remains a lack of disclosure of a flexible connector connecting two clips as described above.

In view of the foregoing deficiencies of the primary reference, and the lack of remedy of these deficiencies from Pyka and Krajicek, a prima facie case of obviousness has not been

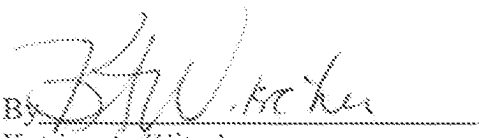
established. Therefore, Applicants respectfully request review and withdrawal of the rejections of claims 17, 19, 20, 22 and 26 and 28.

CONCLUSION

Applicants note with appreciation the indication of allowable claims. It is respectfully submitted that all of the pending claims are in condition for allowance, and such action is requested. If the Examiner believes a telephone interview would be useful, please call the undersigned at the phone number below. The Commissioner is hereby authorized to charge any fee determined to be due in connection with this communication, or credit any overpayment, to our Deposit Account No. 13-2546.

Respectfully submitted,

Date: October 5, 2009

By 

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